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THE OPEN UNIVERSITY OF SRI LANKA
FACULTY OF HEALTH SCIENCES
THE DEPARTMENT OF PHARMACY
THE ACADEMIC YEAR 2023/ 2024 – SEMESTER I

BACHELOR OF PHARMACY HONOURS
FMU5205 – PHARMACEUTICAL ANALYSIS II – LEVEL 5
FINAL EXAMINATION
DURATION: TWO (02) HOURS

DATE: 26TH MARCH 2024 TIME: 09.30 A.M. – 11.30 A.M.

Part B – Short Answer Questions (20 Marks)

1.

1.1 What is meant by total quality management? (01 marks)

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1.2 State the three (03) main components of a Quality Management System. (03 marks)

I.....

II.....

III.....

1.3 State three (03) objectives of Quality Control (QC) in pharmaceutical industry. (06 marks)

I.....

II.....

III.....

2.

2.1 Name two (02) Quality Control (QC) tests which are specifically applicable for pharmaceutical emulsions. (02 marks)

2.2 Answer the following questions regarding the sedimentation volume test.

2.2.1 Name the pharmaceutical- formulation type which uses the sedimentation volume test.

(02 marks)

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2.2.2 Sedimentation volume (F) of a suspension is calculated by F = Vu/Vo (ratio of the ultimate volume of sediment (Vu) to the original volume of sediment (Vo) before settling).
What do the following F values indicate in the context of sedimentation volume of a suspension?

(06 marks)

F=1.....

F=0.5.....

F>1.....

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Part C – Structured Essay Questions (60 Marks)

1.

1.1 State four (04) visual identification tests conducted for solid dosage forms. (04 marks)

1.2 Differentiate between "uniformity of mass" and "uniformity of content" in pharmaceutical preparations. (06 marks)

1.3 Discuss the importance of organoleptic properties in the evaluating of the quality of solid dosage forms, focusing on colour and odour. (05 marks)

1.4 Write short notes on the following topics. (15 marks)

a. Softening time test of rectal suppositories
b. Droplet size test for liquid dosage forms
c. Microbiological limit test

2.

2.1 What are pharmaceutical impurities? (04 marks)

2.2 Give the classification of organic impurities in pharmaceuticals. (04 marks)

2.3 Briefly explain one of the types mentioned in 2.2 classifications. (04 marks)

2.4 Write a short note on "Methods to overcome impurity related problems". (08 marks)

2.5 How sterile product manufacturing premises are designed to prevent dust accumulation and maintain sterility? (10 marks)